K103483

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

GENERAL INFORMATION

Company Name:	Philips Medical Systems (Cleveland), Inc. 595 Miner Rd. Cleveland, Oh 44143
Registration No.:	1525965
Contact Name:	Eduard Toerek Tel: (440) 483-7672 Fax: (440) 483-4918 Eduard.toerek@philips.com
Classification Name:	Emission Computed Tomography System (21 CFR 892.1200) Magnetic Resonance Diagnostic Device (21 CFR 892.1000)
Device Generic Name:	System, PET/MR
Device Trade Name:	Philips Ingenuity TF PET/MR
Classification:	Class II
Product Code	OUO
Performance standards	NEMA voluntary standards, FDA MR Diagnostic Device Guidance, Emission Computed Tomography Devices and Nuclear Tomography Systems UL and IEC 60601-1 appropriate safety standards and/or draft standards are used

PREDICATE DEVICE(S)

The predicate device is the GEMINI TF PET/CT (Raptor), K052640 cleared by FDA on October 7, 2005; and the Achieva 3.0T MRI, K063559 cleared by FDA on January 4, 2007.

INTENDED USE

The device is a diagnostic imaging system for fixed or mobile installations that combines Positron Emission Tomography (PET) and Magnetic Resonance Imaging (MRI). The system does not expose the patient to ionizing radiation, only the dose contribution from the PET radiopharmaceutical. The MRI subsystem produces cross-sectional images, spectroscopy images and/or spectra in any orientation of the internal structures of the whole body. The PET subsystem produces images of the distribution of PET radiopharmaceuticals in the patient body (specific pharmaceuticals are used for whole body, brain, and other organ imaging). The PET and MRI portions of the system can be used either as an integrated system or as a stand-alone MRI or PET system.

The MRI subsystem provides data suitable for use in attenuation correction of the PET acquired data.

Image processing and display work stations provide software applications to process, analyze, display, quantify and interpret medical images/data via a single user interface. The PET and MRI images may be registered and displayed in a fused (overlaid in the same spatial orientation) format to provide combined metabolic and anatomical data at different angles. Trained professional use the images in:

- The evaluation, detection and diagnosis of lesions, disease, and organ function such as but not limited to cancer, cardiovascular disease, and neurological disorders.
- The detection, localization, and staging of tumors and diagnosing cancer patients.
- Treatment planning and interventional radiology procedures.

The device includes software that provides a quantified analysis of regional cerebral activity from the PET images.

The MRI provides capabilities to perform interventional procedures in the head, body, and extremities which may be facilitated by MR techniques, such as real time imaging, such procedures must be performed with MRI compatible instrumentation as selected and evaluated by the clinical user.

DEVICE DESCRIPTION

Philips Ingenuity TF PET/MR Overview

The Ingenuity TF PET/MR system combines the Philips Achieva MR (K063559) and the Philips GEMINI PET/CT (Raptor, K052640) technologies. The system utilizes the MR technology to obtain anatomic images of the human body and PET technology to obtain functional images of the human body. The clinical value of the both technologies is enhanced with the ability to fuse the MR and PET images using Philips fusion viewer software to create a composite image for diagnostic study and therapeutic planning. The system also provides tools for the quantification of results of the MR and PET images and provides a means for a simplified review of the fused images.

Magnetic Resonance Imaging is a medical imaging technique that is based on the principle that certain atomic nuclei present in the human body emit a weak relaxation signal when placed in a strong magnetic field and excited by a radio signal at the precession frequency. The emitted relaxation signals are analyzed by the system and a computed image reconstruction is displayed on a video screen.

Positron Emission Tomography uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high resolution, three dimensional images of biochemical and metabolic processes of organs within the body.

The Ingenuity TF PET/MR system consists of two gantries integrating the MR scanner and the PET scanner, a patient table to support the patient, within the gantries, and a scanning console and viewing console at the operator's workstation.

SUBSTANTIAL EQUIVALENCE STATEMENT

It is the opinion of Philips Medical Systems that the Philips Ingenuity TF PET/MR is substantially equivalent to the Philips GEMINI PET/CT (Raptor), K052640 cleared by FDA on October 7, 2005 and the Achieva 3.0T MRI, K063559 cleared by FDA on January 4, 2007. The difference between the two systems is the reduction of patient radiation exposure of CT by using an MRI vs. a CT system.

SAFETY AND EFFECTIVENESS

The Ingenuity TF PET/MR tests to verify equivalence and to support system performance were conducted in adherence with and certification to applicable standards in the IEC 60601-1 series and NEMA – NU2 standards.

CLINICAL STUDIES

Clinical studies verified acceptable image quality from the Ingenuity TF PET/MR that is equivalent to the GEMINI TF PET/CT. The MR-attenuation correction (MRAC) method was validated through phantom, simulated and clinical data.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

NOV 23 2011

Mr. Eduard Toerek
Official Correspondent
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
CLEVELAND OH 44143

Re: K103483
Trade/Device Name: Ingenuity TF PET/MR System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO
Dated: November 4, 2011
Received: November 8, 2011

Dear Mr. Toerek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

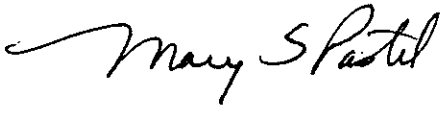
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

K103483

510(k) Number (if known): K103483
Device Name: Ingenuity TF PET/MR System

Indications for Use:

The device is a diagnostic imaging system for fixed installations that combines Positron Emission Tomography (PET) and Magnetic Resonance Imaging (MRI). The system does not expose the patient to ionizing radiation, only the dose contribution from the PET radiopharmaceutical. The MRI subsystem produces cross-sectional images, spectroscopy images and/or spectra in any orientation of the internal structures of the whole body. The PET subsystem produces images of the distribution of PET radiopharmaceuticals in the patient body (specific pharmaceuticals are used for whole body, brain, and other organ imaging). The PET and MRI portions of the system can be used either as an integrated system or as a stand-alone MRI or PET system. The MRI subsystem provides data suitable for use in attenuation correction of the PET acquired data.

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Prescription Use ___X____ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103483